UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,065	05/04/2001	Ward Dean Halverson	101430-0131	8164

21125 7590 12/17/2004

NUTTER MCCLENNEN & FISH LLP
WORLD TRADE CENTER WEST
155 SEAPORT BOULEVARD
BOSTON, MA 02210-2604

EXAMINER	
PADGETT, MARIANNE L	

ART UNIT	PAPER NUMBER
1762	

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/849,065	HALVERSON, WARD DEAN	
	Examiner	Art Unit	
	Marianne L. Padgett	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-8,10-19,21-28,31,33-39 and 49-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-8,10-28,31,33-39 & 49-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/26/04 has been entered.

2. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is noted that in claim 19, line 1, "said tubing" lacks proper antecedent basis due to inconsistent nomenclature, and is assumed to be intended to mean --said tubular article--.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Applicant has amended independent claims 1 and 50 to require that the inner surface of the tubular article (lumen) is being treated and coated, hence removing the 102(b) rejection over Yamazaki (5,601,883) with respect to these claims and previously so rejected dependant claims, because while Yamazaki may treat and coat substrates, such as Al drums

illustrated in Fig. 5 or plastic the "ball pens" or "propelling pencils" (col. 3, lines 43-46), it is the external surface of these articles that are taught to be plasma cleaned (i.e. treated), then plasma coated, via a microwave plasma, meeting ECR conditions and using a magnetic field.

5. Claim 49 remains rejected under 35 U.S.C. 102(b) as being clearly anticipated by Yamazaki (883) as applied in section 4 of paper #9, mailed 3/24/04.

On page 10 of applicant's 7/26/04 response, applicants appear to allege that Yamazaki (883) does not treat and coat any tubular objects. This is clearly incorrect as noted above since that Al drum is clear tubular, with a hollow core, i.e. reads on having a lumen, and only the external surface can be coated, since the holder prevents exposure of any of the inner surface. In claim 49, it does not matter how coating of the interior is prevented. Also the taught coating of the plastic parts for ball-point pens and mechanical pencils, is clearly directed to tubular hollow objects (i.e. having lumens), presumably without the metal parts added, although whether or not they are there is irrelevant to the claims as written, and explicitly teaches coating "the entire external surface". While there is no teaching saying interior coating is excluded, there is no positive teaching that any occurs, but implications are only for external surface treatment of these plastic objects. However, for the purposes of this 102(b) to the generic hollow tubular substrate of claim 49, the Al drum example suffices.

While applicant doesn't appear to be willing to admit that tubular substrates exist in Yamazaki (388) (which makes their arguments unconvincing), their arguments on p.12 of their response appear to be implying that Yamazaki would necessarily or inherently also treat inner surfaces of tubular objects. Note if such an argument were accepted, claims 1, 33 and 50 would be required to be rejected under 102(b) over Yamazaki (388), because while both expose the

inner surface (which applicant's appear to be obliquely implying would be treated, if tubular objects, i.e. pens and pencil tubes were processed), but do not exclude the outer surface from also being treated, which would read on claim 1 and its dependants as previously included. As the examiner does not accept the implications of applicant's page 12 arguments, claim 1 is removed by its amendment from the 102(b) rejection.

Note new claim 54 which also treats and coats the outer surface, is not included because the method of employing a pressure differential to exclude internal coating, is different from using configurational restrictions of the substrate(s) with respect to the plasma, for limiting where coating occurs.

6. Claims 1, 4-8, 10-19, 21-28, 31, 33-39 and 49-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamazaki (883), in view of Subramanian (5,914,115), optionally considering Kieser et al (5,053,244) and/or Wilhelm (4,897,285), as discussed in sections 4, 5, 6 and 7 (esp. 7 for amendments) of paper # 9, mailed 3/24/04.

Note that while independent claims 1, 33 and 50 have been amended to require the at least a portion inner surface of the lumen of a tubular article be ECR plasma treated, and for claims 1, 51 and 50 also be thereafter coated, none of these claims exclude or prohibit coating from also occurring on the outer surface of the substrate, hence are not excluded from Yamazaki (883)'s examples where the interior of the exemplary tubular objects are not plugged up, as by a substrate holder, which prevents gas or plasma gas from entering or flowing through the interior or lumen of the object. However, neither does Yamazaki (883) positively treat or coat any interior part of their exemplary pen or mechanical pencil pieces, since the explicate disclosure is to "entire external surface" with no mention of the internal. For these tubular objects virtually

ignored by applicant's arguments, it would not be unreasonable to suppose, that at least on the ends or edges of the lumen, treating and coating takes place, depending on gas flow characteristics and pressure in the plasma, since gas would inherently be present in their interiors, and as perhaps obliquely implied by applicant's page 12 arguments (but with tubes ignored, application of their arguments to the references is tenuous), but there is no positive necessity for any interior treatment/coating.

Note Yamazaki (883)'s process is applicable to relatively small plastic objects of irregular shapes, inclusive of tubular (with lumens), where plasma treatment is desired. The particular example uses microwave ECR conditions to plasma clean, then carbon coat, but also on col. 6, lines 61-65 notes that glow or arc discharge processes using RF coat, but also on col. 6, lines 61-65 notes that glow or are discharge processes using RF power would also be applicable, so plasma processes using RF glow discharge, such as Subramanian (col. 2, lines 57-67) would have been expected to be effective in Yamazaki (883)'s ECR plasma and configuration, due to taught equivalence. Therefore, as previously combined, the rejection remains applicable to these amended claims, since Subramanian suggest plasma functionalization of surfaces of medical devices inclusive of catheters, vascular stunts, blood transfer devices, etc. (col. 1, lines 57-63, col. 3, line 20; col. 4, lines 1-36, col. 5, line 1 and col. 6, lines 12, 20-32), i.e. substrates both tubular and typically plastic, and where the surface to be treated is any surface that many be in contact with blood when used. Note the structure of the stent illustrated in Fig. 5. Plasma treatment via the ECR plasma and configuration of Yamazaki, using the gases for functionalizing for the specific end use of Subramanian, would clearly provide efficient plasma treatment of both exterior and internal surfaces of the tubular stent, as the gas flow caused by the tumbling action

of Yamazaki (883)'s cylindrical chamber would inherently permeate the very porous structure to treat the lumen's surface.

Kieser et al and/or Wilhelm continue to be optionally applicable for demonstrating known configurations for treating continuous or relatively long tubular substrates with ECR plasma, which relate potentially to long substrates of Subramanian, and ones included in, but not necessarily claimed by applicant's broad category of tubular articles.

7. Claims 21-24 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamazaki (883), in view of Subramanian, optionally considering Kieser et al or Wilhelm as applied to claims 1, 4-8, 10-19, 21-28, 31-39 and 49-52 above, and further in view of Williams et al (4,927,676) or Makker et al (5,942,277) or Narayanan (5,486,357) as cumulatively considered in section 8 of paper #9 and section 10 of paper #6 mailed on 2/21/03.

8. Claims 1, 4, 8, 10, 16-17, 19, 21-22, 24-25, 27-28, 31, 33, 36 and 49-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Conover et al (6,136,389).

Conover et al teach plasma treatment of porous substrates that may be tubular; may be materials such as glass or plastic (or non porous plastic); where the plasma treatment may use gases, such as inert (Ar), H_2, O_2, fluorocarbons, or have an additive exemplified by propylene; plasma may use frequencies from 50 Hz to 10 GHz, where 13.56 MHz is taught useful, but also it is taught "Also well known in the art are potential beneficial modifying means of increasing the ionization potential and/or providing spacial control of the plasma through the use of separate magnetic fields, i.e., electron cyclotron resonance (ECR) microwave plasma technique" (col. 3, line 3-7; claim 11); where the plasma causes decomposition of an organometallic precursor to deposit metal (Pt or Au) on the exposed surface that may be limited to interior or

exterior of tubes. After platinization (metallization) a subsequent coating may be applied, with such suggested coating including plasma polymerized ones or propylene monomers useful in biomedical applications; with suggested applications including Pt/Au coat then attach biological probes, enzymes, and the like (col. 16, lines 30-31). Particularly see, the abstract; col. 2, lines 9-29 and 50-col. 3, line 30 for plasma control; col. 3, lines 31-35 (continuous treatment of tubes) 46-50; col. 4, lines 6-35 and 46- col. 6, line 20, esp. col. 5, line 1-25 (#12 & 13 plasma and single side deposition in tube), 15(a-b) for various subsequent coats, and 17 for biomedical applications. Examples 2, 4, 5, 7, 8-10 (inner tube diameter 7 mm), 15, 16, 17 (A) and 18 directed to tubular substrates, only 16 indicating interior + exterior coating; col. 13, line 64 – col. 14, lines 8 and 63-67 for gases; Col. 15, lines 3-10 for interior surfaces coating, lines 30-40 for applications, lines 51 – col. 16, line 10 for substrate materials and col. 16, lines 11-33 for further coating sequences. Particularly note claims 1, 3-4 and 11-13, with the claimed magnetic field in the reaction zone finding its support in Conover in the disclosure of the optional use of ECR. While the formula in applicant's claim 8 is not given by Conover, it must have been satisfied to produce the taught ECR plasma and the magnetic field must have been selected to do so. Note that noble metals, such as Pt or Au, are generally considered to have anti-microbial or anti-inflammatory properties, hence subsequent complexes made therewith for the bioactive options could be considered inherently inclusive of such properties. Also, plasma treatments due to the energy and radiations involved, inherently affect a sterilization process or effect, regardless of the other intended results.

9. Claims 5-7, 11-15, 22, 25-26, 34-35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conover et al.

Conover et al do not provide specific parameters for use when ECR plasmas are employed, however the magnetic field strengths know to be useful to produce ECR conditions are generally in the claimed range, and Conover et al provide discussion on the importance of control of gas flow and pressure to localize the plasma region and provide a useful guide to adjusting power (Watts) and flow rate according to gases employed and reactor size/shape, hence it would have been obvious to one of ordinary skill in the art to employ such teachings with the ECR option to optimize reaction parameters via routine experimentation, where claimed values would have been within expected optimization.

While the examples where particular internal diameters (ID) as claimed are recited, are not particularly directed to ECR plasma, it would have been obvious to one of ordinary skill in the art to treat such substrates with the option of ECR plasma due to ECR's suggested benefits, and due to the examples suggested desirability of treating substrates of such ID via taught processes.

While the only specifically mentioned attached biological material in Conover is enzymes, bio-affinity operations are taught in general, with specific uses listed as "medical diagnostic... DNA probes, and biopurification and separation operations... application in synthesis... of peptides" (col. 15, lines 28-40), hence when considered with Pt or Au's inherent properties, would have suggested the obviousness of uses where the materials deposited are anti-microbial or anti-inflammatory or effect all growth as claimed, because these teaching suggest the coatings would have properties of these types.

10. Applicant's discussion of new claims on p. 15-16 of the response is noted, and it is further noted that NO attempt to show support for the new limitations appears to have been

made. A quick review of the specification provided that p.9, 2nd paragraph; p. 12, 1st paragraph and p. 13, 2nd full paragraph provide support for new claims 54-58 only coating outside tube surfaces. Discussion on initiating and maintaining plasma within the tube in the ECR zone was found on p. 12, 3rd – 4th paragraphs, but the only support for excluding exterior treatment when treating interior was a general statement in 3rd paragraph in p. 9.

11. Other art of interest includes: Williams et al (5,468,520) who teach sequential ECR plasma coating (2 separate plasma deposited layers) of containers, jars, tubes and medical devices, where coating the surface involves moving the substrate through the plasma zone, but has no discussion of interior or exterior coating, negative or positive (abstract; Fig. 6; col. 6, line 65- col. 8, line 12); Rzad et al (5,156,882) has general pretreatment, then plasma depositions using laminar flow on plastic substrates inclusive of tubes, where ECR is noted to be an additional advantageous refinement (abstract; col. 2, lines 53 – 68+; col. 3, line 38 – col. 4, line 30+; col. 6, lines 4-50+; and col. 10, lines 15-22 (ECR)), but no interior/exterior discussion.

12. Claims 53-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conover et al as applied to claims 1, 4-8, 10-17, 19-22, 24-28, 31, 33-37, 39 and 49-52 above, and further in view of Wilhelm & Kanai et al (5,976,257), & optionally Kieser et al for claim 53.

In teaching platinizing (i.e. plasma treating) interior or exterior, selectively (col. 5, lines 10-30, esp. 15-25), Conover et al does not give specific details, but mention use of "techniques known in the art for 'single side' or 'counter flow' low pressure chemical vapor deposition (LPCVD)... can be modified to obtain controlled platinization layer or zone within the interior wall of the substrate tubing, for deposition at a specific location on or along the wall". While this does not specifically disclose the use of a pressure differential between interior and exterior

of the tube, the terminology suggests that flow hence pressure is involved. Also while directed specifically to porous substrates, the listing of substrates to which Conover et al's process may be applied, also includes non-porous plastic (col. 15, line 65).

ECR plasma are known to be limited by pressure, and use of pressure differentials between areas to be coated and those not to be coated are known in the art, with Wilhelm (discussed previously; abstract; figure; summary) showing use of higher external pressure and lower internal pressure to localize ECR plasma treatment inside a tubular substrate thus treating its interior surface. The Kanai et al reference (Abstract; figures, cover exemplary; col. 21, lines 54 – col. 22, line 55, esp. lines 4-10 and 35-53) use the substrate to create an isolated tubular area that employs a pressure differential to create plasma inside the tube, such that plasma treatment occurs inside, but not outside and that the shape withstands the pressure difference between inside and outside the plasma chamber/ zone. Given these teaching concerning relevant microwave plasmas and use of pressure in localizing where the plasma occurs with respect to a tube shaped substrate to be coated, and consideration of the above discussions/teachings of Conover et al concerning one side coating in low pressure CVD process, it would have been obvious to one of ordinary skill in the art to control the pressure in the tubes of Conover et al, such that only the desired surface, whether interior or exterior (or both) had the correct pressure to sustain the ECR plasma, so that only areas to be coated/ treated were exposed to plasma. Note that this would be easiest with the taught non-porous plastic substrates, but even with porous ones one ordinary skill would have found it obvious to adjust flow and evacuation rates to maintain effective pressure differences, especially considering the teaching of Kanai where mesh or "punching" boards are used in maintaining pressure differences. Kieser et al is optionally

considered for continuous elongated substrate configurations where exteriors are coated, which would have been consistent with Conover et al's own continuous substrate teachings, where the principles expressed in Wilhelm or Kanai et al for localizing plasmas to an interior would apply equally to an exterior where the inside is not to be coated, as it is still the same pressure ranges that make plasma possible or not.

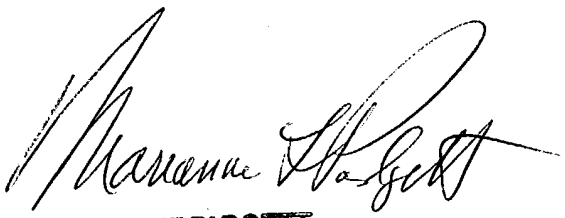
13. Applicant's arguments filed on 7/26/04 and discussed above have been fully considered but they are not persuasive.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. L. Padgett whose telephone number is (571) 272-1425. The examiner can normally be reached on Monday-Friday from about 8:30 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Beck Shrive can be reached on (571) 272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padgett/LR
November 18, 2004
December 14, 2004



MARIANNE PADGETT
PRIMARY EXAMINER